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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,591	09/24/2003	Doug Duchon	57173/1481	5690
7590	03/31/2009	Kramer Levin Naftalis & Frankel LLP 1177 Avenue of the Americas New York, NY 10036	EXAMINER	
			WITCZAK, CATHERINE	
ART UNIT	PAPER NUMBER			
	3767			

MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/669,591	DUCHON ET AL.
	<b>Examiner</b> CATHERINE N. WITCZAK	<b>Art Unit</b> 3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 09 March 2009.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 23-37 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 23-37 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/9/2009 has been entered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 23-25, and 27- 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirschman et al (US 4,854,324).

Hirschman et al discloses an injection device which automatically refills a syringe, the method comprising sensing a volume of fluid in a chamber of the syringe, receiving a preset amount of fluid necessary for a subsequent injection from user input; comparing said volume in said chamber with said preset amount of fluid and retracting a plunger within said chamber of said syringe to a predetermined limit if said preset amount of fluid is greater than the volume of fluid sensed in said chamber, wherein predetermined limit maximally fills said chamber of said syringe, wherein the predetermined limit is less than a maximal volume of said chamber, also comprising the step of the user inputting a safety parameter

related to maximum injection volume, maximum flow rate, maximum pressure and rise time (Abstract, and column 10, lines 16-26. column 13 lines 34-41).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschman et al in view of Reinicke (US 4,684,365).

Even though Hirschman does not explicitly state the step of purging air from the chamber of the syringe attention is directed to Reinicke. The Reinicke reference teaches the step of purging air from the chamber of the syringe col. 7 line 47-51. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the air purging step of Reinicke into the method of Hirschman in order to provide a safer device and to allow for a faster refill.

3. Claims 32-37 are rejected as being unpatentable over Hirschman as applied above, in further view of Riley et al (US 5,672,155).

Hirschman discloses the claimed invention except for the plunger being retracted at a first, slower speed of about 2mL/sec until about 40mL of fluid has been withdrawn, followed by a faster rate of 3mL/sec. Riley teaches in column 12, lines 12-36 that it is known to use an initial slow rate of retraction. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to start with a slow retraction speed as taught by Riley et al in the method of Hirschman in

order to prevent air from being drawn in. [Furthermore, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the speed from a slower rate of 2mL to a faster retraction rate of about 3mL because Applicant has not disclosed that these particular rates (ie 2mL/sec and 3mL/sec) provide an advantage, is used for a particular purpose, or solves a stated problem.

*Response to Arguments*

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witczak/  
Examiner, Art Unit 3767

/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767